REMARKS

This Amendment is responsive to the Office Action dated April 26, 2006. Applicant has amended claims 1-3, 5, 10-12, 14-17, 19-21, 30, 32, 35-39, 46, 53, 62-63 and 68, and canceled claim 34. Claims 1-33 and 35-68 are pending.

Amendment to the Specification

Applicant has amended paragraph **[0029]** of the specification to correct a minor typographical error. No new matter is added by the amendment.

Claim Rejection Under 35 U.S.C. § 112

The Office Action rejected claim 40 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action stated that "the means for generating at least one signal" was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Applicant respectfully disagrees. One example of a means for generating at least one signal described in Applicant's specification is a sensor, examples of which are described throughout the specification.[1]

Claim Rejection Under 35 U.S.C. § 102

The Office Action rejected claims 1-3, 5-8, 10, 11, 13, 19-21, 23-26, 28, 29, 34, 35, 38-44, 46-49, 53-56, 59, 62, 63 and 65-67 under 35 U.S.C. § 102(e) as being anticipated by US 6,773,404 to Poezevera et al. (Poezevera). Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. Poezevera fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

[1] *See, e.g.*, paragraphs [0008] and [0047] [0054].

Claims 1, 19, 39 and 63

For example, Poezevera fails to disclose or suggest determining a value of a sleep metric that indicates a probability of the patient being asleep based on a plurality of monitored physiological parameters, as required by Applicant's independent claims 1, 19, 39 and 63. Instead, Poezevera describes a device that makes a binary determination of whether a patient is asleep or awake based on individual comparison of two physiological parameters to respective thresholds.[2] If the two parameters do not both indicate the same state, i.e., sleep or awake, one of the parameters is further analyzed alone to make the binary determination.[3] However, Poezevera makes no mention of determining a single value of a sleep metric that indicates a probability of the patient being asleep based on the plurality of physiological parameters that are monitored by the device. Accordingly, Poezevera would have failed to even suggest the requirements of independent claims 1, 19, 39 and 63 to one of ordinary skill in the art.

Claims 7, 8, 25, 26, 49 and 56

As other examples, Poezervera also fails to disclose or suggest determining an overall sleep metric based on the values of a plurality of sleep metrics, each of which is determined based on a respective physiological parameter, and determining whether the patient is asleep based on comparison of the value of the overall sleep metric to a threshold, as required by Applicant's claims 49 and 56, or the similar requirements of claims 7 and 25. Further, Poezevera fails to disclose or suggest determining a value of an overall sleep metric by averaging the values of a plurality of sleep metrics, each of which was determined based on a respective physiological parameters as required by Applicant's claims 8 and 26.

In support of these rejections, the Office Action argued that once the plurality of signals is gathered for the physiological parameters, they are averaged to form an overall sleep metric. However, Poezevera describes individually averaging each of the physiological parameters signals over a specified time period.[4] Determining a respective average for each of a plurality of physiological parameters is not the same as determining a value of an overall sleep metric based

[2] Poezevera, Abstract, col. 4, ll. 2-20 and Table 1.
[3] Poezevera, Abstract and col. 4, ll. 20-28.
[4] Poezevera, Abstract and column 5, lines 60-64.

on values of a plurality of sleep metrics, each of which was determined based on respective physiological parameters, as required by Applicant's claims. Accordingly, Poezevera would have failed to even suggest the requirements of claims 7, 8, 25, 26, 49 and 56 to one of ordinary skill in the art.

Claims 10, 28, 43, 48, 55 and 66

As another example, Poezervera also fails to disclose or suggest comparing the value of the sleep metric to a threshold value and determining whether the patient is asleep based on the comparison, as required by claims 10, 28, 43, 48, 55 and 66. For at least the reasons discussed earlier in this Amendment, Poezervera fails to disclose or suggest determining a value of a sleep metric that indicates a probability of the patient being asleep based on the physiological parameters monitored. Poezervera's teachings related to a threshold are limited to comparison of physiological parameter values to a threshold, rather than a sleep quality metric that indicates a probability of the patient being asleep. Poezervera certainly does not even suggest comparing the value of a sleep metric that indicates a probability to a threshold value, and determining whether the patient is asleep based on the comparison, as required by Applicant's claims 10, 28, 43, 48, 55 and 66.

Claims 11, 29 and 67

Additionally, Poezervera makes no mention of comparing the value of a single sleep metric to a plurality of thresholds, as required by Applicant's claims 11, 29 and 67. Instead, as made clear in the portion of Poezervera cited in the Office Action, Poezervera teaches individually comparing each of two physiological parameters to a single respective threshold.[5] Accordingly, Poezervera would not have suggested comparing a single sleep metric to a plurality of thresholds, as required by Applicant's claims 11, 29 and 67, to a person of ordinary skill.

[5] Poezervera, col. 4, ll. 4-27.

Claim 13

Applicant's claim 13 requires a threshold value selected by the user. In support of the rejection, the Office Action simply asserted, naked assertion. Poezevera discloses a predetermined physiological threshold.[6] Poezevera makes no mention of a threshold value selected by the user of the Poezevera device.

Claims 46 and 53

As another example, independent claim 46, as amended, requires monitoring a physiological parameter of a patient via an implantable medical device, wherein the physiological parameter comprises one of blood pressure, muscular activity, arterial blood flow, and galvanic skin response, and determining whether a patient is asleep based on the physiological parameter. Similarly, independent claim 53, as amended, requires a sensor to generate a signal as a function of a physiological parameter of a patient, wherein the physiological parameter comprises one of blood pressure, muscular activity, arterial blood flow, and galvanic skin response, and an implantable medical device that includes a processor to monitor the physiological parameter based on the signal and determine whether a patient is asleep based on the physiological parameter. Poezevera makes no mention of monitoring blood pressure, muscular activity, arterial blood flow, or galvanic skin response.

Poezevera fails to disclose each and every limitation set forth in claims 1-3, 5-8, 10, 11, 13, 19-21, 23-26, 28, 29, 34, 35, 38-44, 46-49, 53-56, 59, 62, 63 and 65-67. For at least this reason, the Office Action has failed to establish a prima facie case for anticipation of these claims under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

[6] Poezevera, Abstract.

Claim Rejections Under 35 U.S.C. § 103

The Office Action rejected claims 4, 22 and 64 under 35 U.S.C. § 103(a) as being unpatentable over Poezevera in view of US 6,752,766 to Kowallik et al. (Kowallik); rejected claims 9 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Poezevera in view of US 5,645,053 to Remmers et al. (Remmers); rejected claims 12, 30 and 68 under 35 U.S.C. § 103(a) as being unpatentable over Poezevera in view of US 5,732,696 to Rapoport et al. (Rapoport); rejected claims 14-18, 32, 33, 36, 37, 45, 50, 51, 52, 57, 58, 60 and 61 under 35 U.S.C. § 103(a) as being unpatentable over Poezevera in view of US 2002/0193697 by Cho et al. (Cho); and rejected claim 31 under 35 U.S.C. § 103(a) as being unpatentable over Poezevera in view of US 6,296,606 to Goldberg et al. (Goldberg).

Applicant respectfully traverses these rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

As an initial matter, Applicant notes that none of Kowallik, Remmers, Rapoport, Cho and Goldberg provides any teaching that would have overcome the basis deficiencies of Poezevera with respect to the requirements of Applicant's independent claims identified above. Each of dependent claims 4, 9, 12, 14-18, 22, 27, 30-33, 36, 37, 45, 50, 51, 52, 57, 58, 60, 61, 64 and 68 is patentable for at least that reason. Further, Applicant notes that the applied references fails to disclose or suggest a number of the requirements recited in these dependent claims.

Claims 9 and 27

For example, the teachings of Poezevera and Remmers are so unrelated that Applicant fails to see why a person of ordinary skill would have looked to Remmers for any modification of the Poezevera device. Remmers teaches techniques for estimating the onset of respiration, which are completely unrelated to determining whether a patient is asleep according to the teachings of Poezevera. Applicant also respectfully disagrees with the Office Action's characterization of

Remmers as teaching use of a weighting value for respiration rate. Instead, Remmers teaches use of a weight of 32 seconds for mean values of estimations of start of inspiration.[7]

Further, Poezevera does not suggest that the different physiological parameters monitored by its device are in any way combined, e.g., averaged, across the different physiological parameters. Remmers lacks any teaching that would have overcome this basis deficiency of Poezevera. In other words, the mere teaching of use of a weighting value for a purpose completely unrelated to teachings of Poezevera would not have suggested applying a weighting value to at least one of a plurality of sleep metrics, each of which is determined based on a respective physiological parameter, as required by claims 9 and 27. Absent some teaching suggesting combination of a plurality of sleep metrics, each of which is determined based on a respective physiological parameter, one of ordinary skill in the art would have seen no reason to modify the Poezevera device to use a weighting value.

Claims 12, 30 and 68

As another example, the Poezevera in view of Rapoport fails to disclose or suggest determining whether a patient is in on of a REM sleep state or a NREM sleep state, as required by claims 12, 30 and 68. The Office Action has not established any suggestion or motivation to modify the Poezevera device to determine whether a patient is a REM or NREM sleep state. The alleged motivation cited in the Office Action is not found in the evidentiary record. Contrary to the Office Action, Rapoport does not suggest determining whether a patient is within a REM or NREM sleep stated in order to determine when to apply a therapy or to give insight into how soon the patient will awake.

The Court of Appeals for the Federal Circuit has addressed the evidentiary standard required to uphold an obviousness rejection.[8] Specifically, the Federal Circuit stated: "[the] factual question of motivation is material to patentability, and (can) not be resolved on subjective belief and unknown authority.[9] This finding must instead be based upon substantial evidence in the record.[10] Such evidence is lacking in the present case.

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[7] Remmers, col. 10, ll. 40-44.
[8] *In re Lee*, 61 USPQ2d 1430 (CAFC 2002).
[9] *Id.* at 1434.
[10] *Id.*

Claims 37and 61

Contrary to the Office Action, Cho does not suggest wireless communication between a sensor and an implantable medical device. Paragraph [0033] of Cho merely indicates that a sensor may be separate from an implantable medical device, e.g., connected by a lead, but does not suggest a wireless connection.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 4, 9, 12, 14-18, 22, 27, 30, 31, 32, 33, 36, 37, 45, 50, 51, 52, 57, 58, 60, 61, 64 and 68 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: July 14, 2006

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